In-process Testing Redesign in Packaging Line of Oral Solid Dosage

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Abstract

Redesign the in-process testing activities in packaging process area to reduce waste and increase the efficiency without compromising the product quality.
A total of two (2) years (April 2017 to April 2019) of in-process tests results of two (2) products are gathered and statistically evaluated. Quality historical data from those in-process testing resulted in a low occurrence of quality events. Descriptive statistic from the historical data was evaluated against current Acceptable Quality levels.
It demonstrated that the current sampling frequency (every 30 minutes) can be changed to a reduce mode inspection[1].

Introduction

The in-process inspection in our packaging lines had been under a "hyper care" process since 2011, when the actual sample size and frequency was established.
It can be expected that at the long run, any process tends to be more in control and stable in term of the expected quality requirements (qualitative and quantitative variables). Consequently, an improvement in the efficiency and efficacy of the process is expected.
At this stage, is required to evaluate if the process historical quality performance provides for the identification of the redundancy and/or non-value activities to address the seven classical wastes categories described in the practices of Lean Manufacturing Philosophy[2]. Inspection steps within any manufacturing activity are considered a non-valued-added activity under Over -processing waste category.

Background

The current in-process testing requires a series of labor intensive activities such as; sample withdraw, visual inspection, measurement inspection thru the use equipment, documentation using data entry, artifact handling, units handling (discard or returned the tablet to the process as applicable). All those activities should be executed within a 30 minutes time interval or less by packaging personnel.
The current state of the in process is that the sample size and the in process testing frequency in each of the four (4) stations is as follows: 10 bottles each 30 minute for the Capper, Retorque and Labeler stations, and 10 bundles each 30 minute for Bundler station.
The Retorque, Labeler and Bundle In-process testing are performed in the secondary packaging area.
The scope of this project is the evaluation of the in-process testing at the Capper Station, which performed in the Primary packaging area. . The In-Process testing performed in the Capper station are: cap and bottle appearance, removal torque verification, cotton presence verification, tablet count verification and appearance verification.

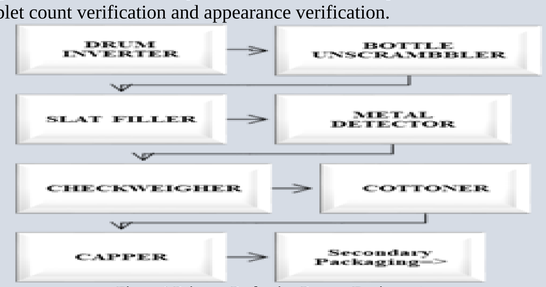

Figure 1 Primary Packaging Process Equipment

Problem

Voice of the Customer (VOC)

For Operations:
Reduce to 50% the cost related with the in-process inspection Personnel available to focus in process improvement and prevention.
For Customers:
The product should comply with the customer expectation without compromising the quality and packaging functionality.
For Quality:
The redesign should not provide an increase in the defective unit found by Quality during their final sampling inspection neither increase, the complaint reports for the defect evaluated in the Capper Station.

Methodology

A multidisciplinary team was ensembled to gather historical data (from sources as batch record and inspection forms) of two (2) product processed in Packaging Line Capper Station. A total of two (2) years (April 2017 to April 2019) of in-process tests results were gathered and statistically evaluated. The in-process inspection results from twenty-two (22) POTTS and eighty-two (82) STARKS batches were analyzed.
The data was tabulated and segregated by quality attribute defects. As well, the complaint historical data for the defect related to quality attribute that are verified in the Capper station were gathered and evaluated. In addition, the cost related to materials and manpower were identified.

Supplier	Input	Process	Output	Customer
• Material Components -Supplier • Tablets -Manufacturing Area	• Procedures • Material Components • Tools • Packaging Order • Packaging Personnel • Batch Record	• Parameter challenges after equipment setting up • Bottle unscrambler and position • Tablet dispensing • Bottle weight (Tablet counting) • Cotton addition • Cap and Torque application • Induction Sealing • Retorque • Label and Outsert application • Label Printing and inspection • Bundle preparation and printing • Case Packaging • In-process test • AQL QA inspection test	• Packaged product • Batch documentation • Waste	• Drug stores • Patient

Figure 2 SIPOC

Collected Data – Quality Attribute

Table 1 POTTS Product quality attribute data (unit = bottle)

POTTS Products Summarized Data					
Total Quantity of Manufactured Batches	Quantity of in-process test per lot	Total Sample units per lot	Total Torque Removal Defective Units	Total Cap & Bottle Appearance Defective Units	Total Tablet Count Defective Units
22	284	2840	0	0	0

Table 2 STARKS product quality attribute data (unit = bottle)

STARKS Products Summarized Data						
Total Quantity of Manufactured Batches	Quantity of in process test per lot	Total Sample units per lot	Total Torque Removal Defectives units	Total Cap & Bottle Appearance Defective units	Total Cotton Presence Defective Units	Total Tablet Count Defective units
82	1556	15560	0	0	0	0

Table 3 POTTS product quality inspection attribute data (unit = tablet)

POTTS Products Summarized Data					
Total Quantity of Manufactured Batches	Quantity of in-process Test	Bottles per IP Test	Units per bottle	Total Sampled Units	Total Tablet Appearance Defective units
22	284	10 bottles per IP test	3 batches -14 units per bottle 19 batches - 60 units per batch	143,720	0

Table 4 STARKS Product quality inspection attribute data (unit =

STARKS Products Summarized Data					
Total Quantity of Manufactured Batches	Quantity of in-process Test	Bottles per IP test	Units per bottle	Total Sample Units	Total Tablet Appearance Defective units
82	1554	10 bottles per IP test	30 units/bottle	466,200	1

Collected Data – Costs

The cost related to materials and manpower to perform the in-process check were gathered to evaluate the actual cost to perform the activity and eventually compare with cost after the Implementation of the redesign project. The cost did not include the tablet costs, the manufacturing process costs neither the packaging process costs.

Results and Discussion

Current Sampling Plan

There are four categories for defects, those are Critical, Major A, Major B and Minor. The worst-case scenario was use for this project and the assumptions was established considering all the defects as critical, refer to tables below for the critical defect category sampling plan. These tables present the current acceptance sampling plan for Critical Defect.

Table 5 Normal Sampling Plan for critical defect (Bottles)

Normal Sampling Plan for Bottles			
Defect Category	Sample Size	AQL	Acc/Rej
Critical	80	0.064%	0/1

Table 6 Normal Sampling Plan for critical defect (Tablets)

Normal Sampling Plan for Tablets			
Defect Category	Sample Size	AQL	Acc/Rej
Batch size < 500,000 tablets			
Critical	800	0.0064%	0/1
Batch size > 500,000 tablets			
Critical	1250	0.0041%	0/1

Test and Confidence Interval for Proportion

Descriptive Statistics

N	Event	Sample p	95% Upper Bound for p
18400	0	0.000000	0.000163

Test

Null hypothesis	H_0: p = 0.5
Alternative hypothesis	H_1: p < 0.5

Figure 3: 95% Bound Estimated – Caps and Bottle Appearance, Torque Removal, and Defective Counts

Summary of Defects Related to Caps and Bottle Appearance, Torque Removal, and Defective Counts for STARKS and POTTS

- A total of 18,400 bottles were sampled as part of the in-process inspection. No defects related to caps and bottle appearance, torque removal, and defective counts were observed out of the 18,400 bottles evaluated during the in-process quality inspection performed during the review period.
- The upper 95% bound estimated for the percentage on defects related to caps, bottle appearance, torque removal, and bottles with defective counts observed (0.0163%) was significantly lower than 95% acceptable quality level AQL (0.064%) established for critical defects in Visual Inspection procedure .

Descriptive Statistics

N	Event	Sample p	95% Upper Bound for p
15560	0	0.000000	0.000193

Test

Null hypothesis	H_0: p = 0.5
Alternative hypothesis	H_1: p < 0.5

Figure 4: 95% Bound Estimated – Cotton Presence

Summary of Defects Related to Cotton Presence in bottles for STARKS Products.

- No defective units related to cotton presence were observed out of the 15,560 bottles inspected as part of the in-process quality inspection.
- The upper 95% bound estimated for the percentage on defects related to cotton presence observed (0.0193%) was significantly lower than 95% acceptable quality level AQL (0.064%) established for critical defects in Visual Inspection procedure.

Descriptive Statistics

N	Event	Sample p	95% Upper Bound for p
143720	0	0.000000	0.000021

Test

Null hypothesis	H_0: p = 0.5
Alternative hypothesis	H_1: p < 0.5

Figure 5: 95% Bound Estimated – Tablet Appearance (POTTS Product)

Summary of Defects Related to Tablet Appearance for POTTS Products

- For defects related to cotton presence, no defective units were observed out of the 143,720 bottles inspected as part of the in-process quality inspection.
- The upper 95% bound estimated for the percentage on defects related to cotton presence observed (0.0021%) was significantly lower than 95% acceptable quality level AQL (0.0064% / 0.0041%) established for critical defects in Visual Inspection procedure.

Descriptive Statistics

N	Event	Sample p	95% Upper Bound for p
466200	1	0.000002	0.000010

Test

Null hypothesis	H_0: p = 0.5
Alternative hypothesis	H_1: p < 0.5

Figure 6: 95% Bound Estimated – Tablet Appearance (STARKS Product)

Summary of Defects Related to Tablet Appearance for STARKS Product

- For defects related to tablet appearance, one (1) defective units was observed out of the 466,200 bottles inspected as part of the in-process quality inspection.
- The upper 95% bound estimated for the percentage on defects related to cotton presence observed (0.0010%) was significantly lower than 95% acceptable quality level AQL (0.0064% / 0.0041%) established for critical defects in Visual Inspection procedure

Conclusions

The in-process inspection results demonstrated that the Primary Packaging Process is capable of produce lots that will be consistently in compliance with the sampling plan acceptance criteria. According to the switching rules described in the ANSI/ASQ Z1.4, the current sampling frequency (every 30 minutes) can be changed to a reduce mode inspection. The implementation of the propose sampling scheme represents a cost saving of approximately 90% from the current costs for STARKS and a cost saving of 85% for POTTS products.

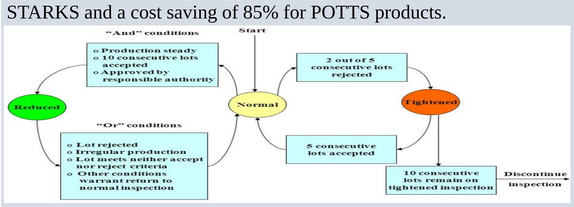

Figure 7 Switching Rule

Future Work

Extend this evaluation to the Secondary Packaging Process area and evaluate the implementation of statistical process Control Charts for the removal torque inspection as preventive action tool in the Primary Packaging process.

Acknowledgements

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References

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